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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,542	07/27/1999	DOUGLAS JOSEPH DOBROZSI	7247M	5652

27752 7590 10/09/2002

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/361,542	DOBROZSI, DOUGLAS JOSEPH	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41 and 336* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time, and the Amendment E, both received by the Office on July 9, 2002.

Applicant's response is confusing regarding the cancellation of the previous claims. Applicant states once that claims 31, and 33-35 are to be canceled. However, in the discussion and response, it is stated that claims 30-35 have been canceled. It appears by the newly added claims that claims 30-35 were to be canceled, and this is how the response has been interpreted.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 38, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,980,175 to Chavkin *et al.*. Chavkin *et al.* disclose an oral, liquid composition for suspending orally administratable pharmaceutical active compositions comprising colloidal silicone dioxide (abstract), more specifically fumed silicon dioxide (c 3, l 68). Chavkin *et al.* also teach that the pharmaceutical active can be selected from gastrointestinal agents, as well as mucosal bioadhesives (c 8, claim 10). Chavkin *et al.* further teach that the colloidal silicon should be present at 2% by weight (c 4, ex. 1).

Chavkin *et al.* teach a bio-adhesive composition, which sticks to moist mucosal surfaces and holds medication at that site for controlled release (c 2, l, 58-65). Furthermore, Chavkin *et al.* teach that their composition has a much longer residence time in the stomach, which makes for a much longer duration of the active ingredient. It is the position of the examine that Chavkin *et al.* teach applicant's claimed method of administering an active agent to one or more of the esophagus, stomach, and small intestine, by swallowing a composition comprising colloidal silica and an active agent.

It is acknowledged by the examiner that Chavkin *et al.* do not teach colloidal silica as the mucoadhesive compound. However, there is nothing in applicant's instant claim language to require this limitation, therefore allowing the teachings of Chavkin *et al.* to read on the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chavkin *et al.*, as discussed above, and in view of the following comments. Chavkin *et al.* are discussed above as teaching a mucoadhesive composition for administration to the stomach, comprising an active agent and colloidal silicon dioxide.

Chavkin *et al.* do not teach the particular particle size of the collodial silica. However, absent a clear showing of criticality, the determination of the particular particle size is considered to be within the skill of the ordinary worker as part of the process of normal optimization, and is not found to shed patentable distinction on the claim.

Additionally, Chavkin *et al.* do not specifically teach the inclusion of citric acid. However, Chavkin *et al.* do teach that conventional additives can be added to the composition, (c 4, l 1-6). Absent a showing of criticality, based on this particular additive, it is the position of the examiner that the inclusion of a well known pharmaceutical excipient, such as citric acid, does not render patentable weight to the claim. Any showing of unexpected results must be shown to accrue from the specific limitation.

One of ordinary skill in the art would have been motivated to a composition for administration to the stomach, wherein the composition comprising particles of colloidal silicon dioxide, an active agent, and well known excipients, based on the teachings of Chavkin *et al.*. One of ordinary skill in the art would except the composition to allow for much longer residence time in the stomach, which makes for a much longer duration of the active ingredient, based on the teachings of Chavkin *et al.*. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Applicant canceled the claims drawn to a method of providing a mucoadhesive coating to mucosa, and replaced them with claims drawn to a method of administering an active

agent. Therefore, the new claims are drawn to an entirely different method. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. E. Pulliam
Patent Examiner
Art Unit 1615
October 4, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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